

### **Remarks/Arguments**

Claims 1-4 and 11-14 are pending. Claims 5-10 and 15-20 have been withdrawn in response to the restriction requirement. Claim 11 has been amended to be free of dependencies upon withdrawn claims. Applicants respectfully submit that the amendment made herein adds no new matter to the application and is supported by the specification as originally-filed. The amendment is made in a good faith effort to advance the prosecution on the merits of this case. It should not be assumed that the amendment was made for reasons relating to patentability.

Applicants respectfully request that the above amendment be entered, and further request reconsideration of the application in light of the remarks contained herein. Applicants thank the Examiner for her careful consideration of this application.

Claims 1-4 and 11-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Mathias U.S. Patent No. 6,387,086 (hereinafter the "Mathias") in view of Ishida U.S. Patent No. 5,125,920 (hereinafter "Ishida"). Claim 13 has also been rejected over the combination of the Mathias and Ishida, further in view of Patel U.S. Patent No. 5,167,657 (hereinafter the "Patel"). Applicants respectfully traverse these rejections of the pending claims.

The Office Action fails to state a *prima facie* case of obviousness. Specifically, the prior art references do not teach or disclose the limitation of a bag system for collecting a biological fluid including...at least two identification tags, one on the collection bag and one on the sampling receptacle, as required by independent claim 1. The Office Action acknowledges that Mathias does not teach identification tags, contending that "Ishida teaches a collection bag with identification tags." Office Action, p. 3. Ishida, however, does not teach or disclose a bag system that includes at least one tag on the collection bag and at least one tag on the sampling receptacle, as recited in Applicants' claim. Rather, Ishida teaches multiple labels which are subsequently affixed to the surface of the blood collection container. Ishida col. 2, lines 60-63.

The Office Action further contends that "[t]he claim only requires that the tags allow the establishment, after their dissociation, that the collection and receptacle [sic] bag originated from the same system." This is an incorrect interpretation of the claim. The interpretation of claim terms should be made according to the plain meaning of the term unless

such meaning is inconsistent with the specification. MPEP § 2111.01. “Plain meaning” refers to the ordinary and customary meaning given to the term by those of ordinary skill in the art. *Id.* One of ordinary skill in the art would understand the plain meaning of the terms of independent claim 1 to indicate that, when the bag system is removed from the sterile package, the collection bag and the sampling receptacle both already have tags on them. Thereby, handling errors on the part of a user may be minimized. As discussed in Applicants’ specification at ¶ [0008], handling errors are more probable when users must place labels on the bags/receptacles themselves and/or are handling large numbers of bag systems. Notably, Ishida teaches-away from the plain meaning of the terms of independent claim 1. As discussed in Applicant’s Response to Non-Final Office Action Mailed July 16, 2007, in distinguishing the prior art, Ishida states:

[I]n the case that labels are previously stuck on the blood collecting tubes prior to blood collection works, there is a possibility that blood is collected into a blood collecting tube from a wrong blood bag, that is, a blood bag provided with the label having a different serial number from that of the label on the blood collecting tube into which blood is collected.

Ishida col. 1, lines 36-42. Moreover, the interpretation of the claim terms proposed in the Office Action would be inconsistent with their use in the specification, which indicates that the tags are put on the collection bag and the sampling receptacle “at the time of manufacture.” Applicants’ specification at ¶ [0053]; figures 8A and 8B. In contrast, Ishida teaches that tags should be stuck on the surfaces of the blood collecting tubes immediately prior to, or immediately following, blood collection. Ishida col. 5, lines 16-23 and 37-39. As Ishida only discloses a user placing a tag on the collection bag and the sampling receptacle, handling errors may occur. Therefore, neither Mathias, Ishida, nor the references taken together teach or disclose a bag system for collecting a biological fluid including...at least two identification tags, one on the collection bag and one on the sampling receptacle.

The prior art references also fail to teach or disclose confining the bag system in a sterile fashion in a package, as required by independent claim 1. The Office Action contends that “Mathias teaches the components are pre-sterilized and teaches the importance of a sterilized system (col. 1, lines 39-41 and lines 49-53).” Nevertheless, such a teaching still fails to disclose an entire bag system that is confined in a sterile fashion in a package at the time of manufacture. For example, Mathias’ sampling vial 70 is could not be confined with the system in a sterile

fashion, since it is not even added to the system until the time of a collection procedure. Mathias col. 7, lines 36-42. Moreover, a thorough review of Mathias and Ishida fails to find any teaching of a package confining the bag system. Even if Mathias and Ishida were to teach a package, such a package could not confine the required bag system in a sterile fashion. As previously discussed, Ishida teaches that a user places a tag on the collection bag and the sampling receptacle. The user, thereby, voids the sterility of the system by way of adding the tag to the sampling receptacle. Therefore, the combination of Mathias and Ishida does not teach or disclose a bag system which includes an identification tag on the sampling receptacle being confined in a sterile fashion in a package.

With respect to claim 13, the Office Action further contends that Patel discloses transparent flexible plastic bags at col. 6, lines 33-39. Patel, however, teaches donor bags (Patel col. 3, line 59), transfer bags (Patel col. 4, line 9), and blood bags (Patel col. 4, line 16), each of which are intended to store red blood cells (Patel col. 3, lines 59-62). Like Mathias and Ishida, Patel fails to disclose a package confining the bag system. As the references fail to teach a package confining the bag system, there can be no teaching, suggestion, or motivation in any of the references to confine the bag system in a package in a sterile fashion. Likewise, as previously discussed, prior art teaches-away from confining the bag system in a package in a sterile fashion (*see, for example*, Ishida col. 1, lines 36-42). Therefore, it would not have been obvious to one of ordinary skill in the art at the time of the invention to combine the references while adding-in the previously unknown elements of a package and wherein the bag system is confined in a sterile fashion in the package.

The Office Action fails to state a *prima facie* case of obviousness due to the fact that the cited prior art references, even when combined, fail to make obvious each of the limitations of independent claim 1. Therefore, independent claim 1 is believed patentable over the prior art of record. Since claims 2-4 and 11-14 depend, either directly or through an intermediate claim, on independent claim 1, they are also believed to be patentable over the prior art of record for the same reasons given above.

**Summary**

In light of the above remarks, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections. Applicants further submit that the application is now in condition for allowance, and earnestly solicit timely notice of the same. Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to contact the attorney of record.

Applicants believe that there are no fees due in association with this filing of this Response. However, should the Commissioner deem that any additional fees are due, including any fees for extensions of time, the Commissioner is authorized to debit Baker Botts L.L.P. Deposit Account No. 02-0383, Order Number 069208.0117, for any underpayment of fees that may be due in association with this filing.

Respectfully submitted,

BAKER BOTTS L.L.P. (023640)

By: Shannon Powers

Shannon Powers

Registration No. 59,584

BAKER BOTTS L.L.P.

One Shell Plaza

910 Louisiana

Houston, TX 77002

Telephone: 713.229.1193

Facsimile: 713.229.7793

Email: shannon.powers@bakerbotts.com

Date: April 3, 2008